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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,973	09/21/2001	Peter John Hylands	117-360	9598

7590 08/13/2003

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EXAMINER
GAKH, YELENA G

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,973	HYLANDS ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the process involving comparative analysis of the proteins of target cells with and without effect of the medicinal plant material (proteomics analysis of the tissue cells), does not reasonably provide enablement for the process which does not involve this method step. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. No one of ordinary skill in the art can perform the proteomics analysis for defining biological activity of the medicinal plant without introducing the target cells and comparing the results of the analysis for the affected and unaffected target cells.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 recite "preparing a test extract" of the medicinal plant, while the process should be conducted such that NMR data reflect "the totality of the compounds in the plant material". Any extract has an altered composition compared to the original plant, and therefore these limitations contradict each other.

In claim 2 it is not clear, how the candidate sample can have parameters, which comply with the standard specification obtained by the method of claim 1, when no proteomics is

performed for the candidate sample, and therefore it is not clear, if its biological activity complies with the biological data for the standard.

In claim 3 it is not clear, what is meant by the compliance of the biological data of the candidate sample with those of the standard, as no criteria for such compliance is disclosed in the specification. It is not clear, if biological profile should be exactly the same as the one of the standard, or there can be any specific deviation from such profile, and in this case what deviation this might be, etc.?

In claim 7 it is not clear, what a "purifying the test solution or test extract of the sample" might mean? The specification discloses in one of the examples removing caffeine from tea plants to get reliable results from a multivariate analysis of their NMR spectra. It is not a "purifying" the test solution in its conventional meaning, since caffeine cannot be considered an impurity in the tea extracts. If a pre-treatment of the test extract is necessary for improving clustering of data obtained by the multivariate analysis, this should be clearly recited in the claim.

In claims 1-8 it is not clear, if any correlation between the NMR data analyzed by multivariate techniques and biological profile of the standards and test samples is determined, or these are completely independent characteristics of the plant material and thus are not necessarily defined simultaneously?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 9-11 and 15** are rejected under 35 U.S.C. 102(b) as being anticipated by Vercauteren et al. (WO 96/18911).

Vercauteren teaches a process of providing a standard specification for a medicinal plant material (page 3, lines 19-24 and page 9, line 23 - page 10, line 4), as well as a method of

establishing a compliance of the test sample with such specification, which comprises obtaining NMR data on the standard (and the test sample, claim 1 and Figure 1) and applying multivariate analysis, principal component analysis in particular, to these NMR data (page 16, line 23 - page 18, line 3) to generate one or more score points (Figure 6). NMR spectra intrinsically reflect the totality of the NMR responsive compounds in the plant material. The method further comprises defining a region of acceptability for the test samples around the points obtained for the standards, which allows establishing compliance of the test samples with the standard specification. Performing the multivariate analysis of claim 9 inherently comprises applying an unsupervised methodology.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 12-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vercauteren.

While Vercauteren does not specifically teach a method wherein the plant material is a mixture of several plants or wherein it is a remedy from a system of traditional medicine, Traditional Chinese Medicine in particular, it would have been obvious for anyone of ordinary

skill in the art to apply his method to more complex mixtures of plants, including those used as remedies in traditional medicine, because such remedies require standardization in the same way as disclosed by Vercauteren for medicine plants, and because multivariate techniques are applied specifically for analysis of complex mixtures.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Yelena Gakh

Yelena G. Gakh
August 11, 2003